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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,231	01/04/2005	Andre Johan Taljaard	930092-2008	5104

7590 11/22/2010
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EXAMINER

MAI, HAO D

ART UNIT	PAPER NUMBER
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3732

MAIL DATE	DELIVERY MODE
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11/22/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,231	Applicant(s) TALJAARD, ANDRE JOHAN	
	Examiner HAO D. MAI	Art Unit 3732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-7,11-14,18,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-7,11-14,18,22 and 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION***Continued Prosecution Application***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/08/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. **Claims 1-2, 5-7, 11-14, 18, and 22-23, are rejected under 35 U.S.C. 103(a) as being unpatentable over Karasic (6,805,127) in view of Bergersen (4,898,535), and further in view of Bertoch et al. (6,755,191).**

Regarding claim 1, Karasic discloses a device capable of retaining a medical tube, the device including: a first patient engaging portion (first mouthguard 14) configured to engage a zone of an upper jaw of a patient; and a second patient engaging portion (second mouthguard 24) configured to engage a zone of a lower jaw of the patient (Fig. 1). Both the first and second engaging portions 14, 24, each is being shaped in a form of a dental arch and having tooth engaging portions; and the two portions are being biased apart to provide a working gap

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between. The device further includes a medical tube guide means, e.g. the tongue retractor holder 62 or throat opener channel/holder 42, either of which is capable of holding a medical tube and is located in an airway of the patient. The medical tube guide means 62 or 42 is supportable on patient engaging portion 24 and located relative to the patient engaging portions such that in use the medical tube guide means is operatively positioned at the mouth of a patient in order to hold the medical tube as it exits the airway of the patient. The device further includes least one bite block, e.g. structure 34/36 or 40, extending from at least one of the patient engaging portion capable of preventing a patient exerting a compressive force on the medical tube.

Karasic fails to disclose the first and second patient engagement portions 14, 24, meeting at an apex and are pivotably displaceable relative to one another. Bergersen discloses a dental appliance¹⁰ having first/upper and second/lower patient engagement portions 26, 30, respectively; wherein the first and second patient engagement portions meet at an apex/biasing hinge 34 and are pivotably displaceable relative to one another (Figs. 1-8; abstract; column 2 lines 57-68). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Karasic by having the first and second patient engagement portions meeting at an apex or hinge as taught by Bergersen as a known alternative suitable connecting mechanism between the first and second patient engagement portions.

Karasic further fails the securing means. Bertoch et al. disclose a clamp 20 (Figs. 1-3) operable between a securing and a releasing position. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Karasic by including a clamp such as that of Bertoch et al. in order to secure the medical tube against longitudinal displacement.

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As to claim 2, Karasic discloses the mouthguards 14, 24 being made from elastomeric material, which are inherently resiliently deformable. **As to claims 5-7**, at least the medical tube guide means 42 is eccentrically located towards a commissure of the mouth and is sized to permit a view into the mouth of the patient through the working gap; it is also capable of immobilize the medical tube in a desired position. **As to claim 11**, wherein Karasic's device is modified by Bergersen for the first and second patient engaging portions being connected, biased, and pivotably displaceable relative to each other via apex/hinge 34; note that Bergersen further discloses the apex/hinge 34 comprises a spring and/or resiliently deformable material (column 3 lines 29-47).

As to claims 12 and 14, Karasic's medical tube guide means 62 or 42 each includes a eye through which the medical tube to be guided can pass; and the first and second patient engaging portions includes portions configured to approximate a patient's bite size.

As to claim 13, Karasic does not disclose a slip resilient portion in the medical tube guide means. Bertoch et al. disclose that the inner surfaces of clamp 20 may be lined with a material having a high coefficient of friction such as rubber, or be formed with protuberances, ridges, grooves, etc. to improve the grip on a medical tube (column 4 lines 25-34). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Karasic by incorporate a slip resilient portion, such as lining the inner surface of the medical tube guide means 62 with a material having a high coefficient of friction in order to prevent slippage movement of the medical tube as explicitly taught by Bertoch et al.

Regarding claim 18, the method comprising the step of biasing a patient's teeth away from the medical tube while permitting the medical tube to be guided into the patient is naturally carried out when using the device disclosed by Karasic and Bertoch et al. as detailed above.

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Regarding claims 22-23, Karasic discloses all the limitations as claimed as detailed above with respect to claims 1 and 5. Particularly, the first and second patient engaging portions 14, 24, each comprises a resiliently deformable arm 34, 36, respectively. Each arm has a base (area near 12) attached at one end, and a tooth engaging portion attached at the other end.

Response to Arguments

4. Applicant's arguments filed 09/08/2010 regarding the newly recited limitation "the first and second patient engagement portions meet at an apex..." have been fully considered but are moot in view of the new ground(s) of rejection in view of Bergersen as detailed above.

Applicant's arguments filed with the Pre-Appeal Brief Request on 06/11/2010 have been fully considered but they are not persuasive. Applicant argued that Karasic's two opposing mouth guards 14, 24 are not biased apart as claimed because Karasic's fastener 12 merely retains the two mouth guards in a stationary position relative one another. The examiner maintains that Karasic's fastener 12 biases the mouth guards 14 and 24 apart as claimed, and/or exerts an opening force exerted there between as argued by Applicant as the meaning of "biased apart". Furthermore, under the new ground(s) of rejection as detailed above, Karasic in view of Bergersen provides the two patient engaging portions or mouth guards being connected and biased apart at an apex/hinge 34 as taught by Bergersen.

Applicant further argued that Karasic's tongue retractor holder 62 or holder 42 cannot be interpreted as a medical tube guide means. As noted in previous Office Actions, if the prior art structure is capable of performing the recited functions or intended use, then it meets the claim. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The examiner maintains that Karasic's holder 62 or 42 is supported on at least one of the patient engaging portions and located relative to the

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patient engaging portions such that in use holder 62 or 42 is operatively positioned at the mouth of the patient, therefore meet the claimed structural limitations of the medical tube guide means. As for the claim language or intended use (i.e. medical tube guide means... for holding a medical tube..., in order to hold the medical tube..., etc.), Karasic's holder 62 or 42 is capable of performing the recited functions or intended use.

Applicant further argued that holder 62 and 42 are not suitable for receiving a medical tube because holder 62 is in the form of an elongate slot, which is unsuitable for a medical tube's a circular circumference; and holder 42 is anchoring throat opener. Such arguments are not persuasive because neither the medical tube nor any structural limitations thereof (e.g. circular circumference) is actively claimed. "A medical tube" is interpreted broadly within reason as any kind of medical tubing device, e.g. a catheter; and a relatively small catheter with a circular or other shape circumference can certainly be received through Karasic's holder 62 and 42.

Applicant's arguments regarding the invention's medical tube guide means in the form of an elongate channel preventing angular displacement of the medical tube are not persuasive because such features are neither recited in the claims nor disclosed in the specification as originally filed.

As to the claimed bite block, The examiner maintains that Karasic's structures 34/36 or 40, each is qualified as the claimed bite block as each is "extending from at least one of the patient engaging portion and is capable of preventing a patient exerting a compressive force on the medical tube" as required/recited by claim 1.

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Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAO D. MAI whose telephone number is (571)270-3002. The examiner can normally be reached on Monday-Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cris Rodriguez can be reached on (571) 272-4964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hao D Mai/
Examiner, Art Unit 3732

/Cris L. Rodriguez/
Supervisory Patent Examiner, Art Unit 3732